

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 13-978 (RGA)
v.)	
)	
WATSON LABORATORIES, INC.,)	
)	REDACTED - PUBLIC
Defendant.)	VERSION

MERCK & CIE, BAYER PHARMA AG and)	
BAYER HEALTHCARE)	
PHARMACEUTICALS INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 13-1272 (RGA)
v.)	
)	REDACTED - PUBLIC
WATSON LABORATORIES, INC.,)	VERSION
)	
Defendant.)	

PROPOSED FINAL PRETRIAL ORDER - PATENT

This matter comes before the Court at a final pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. The parties are Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively “Plaintiffs”) and Defendant Watson Laboratories, Inc. (“Watson”).

Plaintiffs' Counsel:	Jack B. Blumenfeld (#1014) Derek J. Fahnestock (#4705) MORRIS, NICHOLS ARSHT & TUNNELL LLP 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899 Tel: (302) 658-9200 jblumenfeld@mnat.com dfahnestock@mnat.com	Adam K. Mortara J. Scott McBride Rebecca T. Horwitz Faye E. Paul BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP 54 W. Hubbard Street, Suite 300 Chicago, IL 60654 Tel: (312) 494-4400
Defendant's Counsel:	Richard L. Horwitz (#2246) David E. Moore (#3983) Stephanie E. O'Byrne (#4446) POTTER ANDERSON & CORROON LLP Hercules Plaza, 6th Floor 1313 N. Market Street Wilmington, DE 19801 Tel: (302) 984-6000 rhorwitz@potteranderson.com dmoore@potteranderson.com sobyne@potteranderson.com	Steven A. Maddox Jeremy J. Edwards Matthew C. Ruedy MADDOX EDWARDS PLLC 1900 K Street NW, Suite 725 Washington, DC 20006 Tel: (202) 830-0707

TABLE OF CONTENTS

I.	NATURE OF CASE AND PLEADINGS	4
A.	Nature of the Action.....	4
B.	Plaintiffs' Complaints	4
C.	Defendant's Answers & Counterclaims.....	5
II.	JURISDICTION	5
III.	ISSUES OF FACT	5
IV.	ISSUES OF LAW	6
V.	TRIAL EXHIBITS	6
VI.	DEMONSTRATIVE EXHIBITS	8
VII.	WITNESSES.....	10
A.	Live Witnesses	10
B.	Deposition Testimony	11
VIII.	BRIEF STATEMENT OF INTENDED PROOFS	13
IX.	<i>IN LIMINE</i> REQUESTS	13
X.	CERTIFICATION OF SETTLEMENT DISCUSSIONS	13
XI.	MISCELLANEOUS ISSUES	13
A.	Proposed Amendment of the Pleadings.....	13
B.	Stipulations.....	14
C.	Damages	14
D.	Expected Duration and Scope of Trial	15
E.	Type of Trial	15
F.	Order of Proof	16
XII.	ORDER TO CONTROL COURSE OF ACTION	16

I. NATURE OF CASE AND PLEADINGS

A. Nature of the Action

1. This is a consolidated trial of two patent infringement actions. Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively “Plaintiffs”) filed these actions for patent infringement of United States Patent Number 6,441,168 B1 (the “’168 patent”) against Watson Laboratories, Inc. (“Watson”). These actions arise under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). They relate to Abbreviated New Drug Application (“ANDA”) Nos. 203593 and 203594, which Watson filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of Bayer’s Beyaz® and Safyral® oral contraceptive products that are sold in the United States before the expiration of the ’168 patent. The ’168 patent is directed towards specific polymorphic forms of the calcium salt of 5-methyl-(6S)-tetrahydrofolic acid. Plaintiffs assert claim 4 of the ’168 patent against Watson.

2. Watson subsequently Answered and filed declaratory judgment counterclaims against Plaintiffs alleging non-infringement and invalidity of the ’168 patent.

3. Watson has since stipulated to infringement of claim 4 of the ’168 patent, assuming that the claim is not invalid and is enforceable. The only issue to be tried is the invalidity of claim 4 of the ’168 patent.

B. Plaintiffs’ Complaints

4. On or about April 24, 2013, Plaintiffs received a letter from Watson notifying Plaintiffs that Watson had submitted ANDA No. 203594 seeking approval to market a generic version of Safyral®. On or about June 21, 2013, Plaintiffs received a letter from Watson notifying Plaintiffs that Watson had submitted ANDA No. 203593 seeking approval to market a

generic version of Beyaz®. Both notice letters contained a “Detailed Statement of the Factual and Legal Bases for [Watson Laboratories, Inc.’s] Opinion That [the ’168 patent is] Invalid, Unenforceable and/or Not Infringed.”

5. On June 4, 2013 and July 23, 2013, Plaintiffs filed their Complaints against Watson for infringement of the ’168 patent based on Watson’s filing of ANDA Nos. 203594 and 203593 under 21 U.S.C. § 355(j)(2)(B), seeking to obtain approval to commercially manufacture, use, offer for sale, and sell, before the expiration of the ’168 patent, a generic version of the oral contraceptive products Safyral® and Beyaz®, respectively.

C. Defendant’s Answers & Counterclaims

6. On August 2, 2013 and August 19, 2013, Watson filed its Answers, Defenses, and Counterclaims, denying all material allegations asserted by Plaintiffs and seeking a Declaration that it did not infringe the claims of the ’168 patent and that the claims of the ’168 patent are invalid.

7. On February 19, 2014, Watson stipulated to infringement of claim 4 of the ’168 patent, if such claim is found to be valid and enforceable.

II. JURISDICTION

8. This Court has subject matter jurisdiction over all claims and counterclaims in this action pursuant to 28 U.S.C. §§ 1331 and 1338. Subject matter and personal jurisdiction are not disputed.

III. ISSUES OF FACT

9. The parties stipulate to the facts listed in **Exhibit 1**, attached hereto. These stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

10. Plaintiffs' statement of issues of fact that remain to be litigated is attached hereto as **Exhibit 2**.

11. Watson's statement of issues of fact that remain to be litigated is attached hereto as **Exhibit 3**.

IV. ISSUES OF LAW

12. Plaintiffs' statement of issues of law that remain to be litigated is attached hereto as **Exhibit 4**.

13. Watson's statement of issues of law that remain to be litigated is attached hereto as **Exhibit 5**.

V. TRIAL EXHIBITS

14. The list of trial exhibits which may be offered by Plaintiffs, including Watson's objections thereto, is attached hereto as **Exhibit 6**.

15. The list of trial exhibits which may be offered by Watson, including Plaintiffs' objections thereto, is attached hereto as **Exhibit 7**.

16. The parties agree to disclose any supplemental trial exhibits promptly after identification. Reasonable supplementation of trial exhibit lists will be permitted until May 11, 2015, at 5:00PM EDT and all supplemental trial exhibits must be received promptly thereafter. Objections to the supplemental trial exhibits shall be due no later than May 14, 2015, at 5:00PM EDT. Limited and reasonable supplementation of trial exhibit lists will be permitted after May 11, 2015, so long as the opposing party will not be unfairly prejudiced by such supplementation.

17. Each party reserves the right to offer trial exhibits set forth in the opposing party's exhibit list, even if not set forth in its own trial exhibit list. All objections to such trial exhibits are preserved, regardless of whether such exhibits also appear on the objecting party's exhibit

list. Any trial exhibit, once admitted, may be used equally by either party subject to any limitations as to its admission into evidence.

18. The parties agree that exhibits to be used solely for impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used or offered at trial.

19. The demonstrative exhibits the parties intend to use at trial do not need to be described on their respective lists of trial exhibits.

20. Except as otherwise set forth herein, no party may use a trial exhibit not present on **Exhibits 6 or 7** unless the parties agree otherwise or absent good cause shown.

21. The parties reserve their rights to raise all objections to exhibits as set forth on the trial exhibit lists. The listing of a trial exhibit does not constitute an admission as to the admissibility of the trial exhibit (i.e., a waiver of any applicable objection). Each party reserves the right to object to the relevance or admissibility of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered, or for any other reason as set forth in the Federal Rules of Evidence or other applicable principles of law.

22. Each party shall serve on opposing counsel by electronic mail a written list by exhibit number of the trial exhibits that each intends to use during direct examination of a witness, by 7:00PM EDT on the calendar day before such direct examination is expected to take place. The receiving party shall inform the opposing party of any remaining objections to such trial exhibits by 9:00PM EDT of the day received, and the parties shall meet and confer by 10:00PM EDT that evening to resolve the objections. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

23. No exhibit shall be admitted unless offered into evidence through a witness, who must at least be shown the exhibit. At some point before the completion of the witness's testimony, any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence, by exhibit number.

24. Exhibits not objected to will be received into evidence by the operation of the Final Pretrial Order without the need for additional foundation testimony, provided the exhibit is shown to a witness.

25. Any document bearing a party's letterhead or corporate logo or any document that on its face appears to have been authored by an employee, officer or agent of a party and has been produced from that party's files shall be deemed to be *prima facie* authentic, subject to the right of any party against whom such document is offered ("opposing party") to adduce evidence to the contrary or to require that the offering party provide authenticating evidence if the opposing party has a reasonable basis to believe that the document is not authentic.

VI. DEMONSTRATIVE EXHIBITS

26. The parties shall exchange by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered) full color copies of any demonstrative exhibits that each party intends to use at trial in its respective opening statement by 6:00PM EDT on May 17, 2015. The receiving party shall inform the opposing party of any objections to the opposing party's demonstrative exhibits by 8:00PM EDT that same day, and the parties shall meet and confer by 10:00PM EDT that evening to resolve the objections. Any disputes as to demonstrative exhibits to be used in opening statements shall be raised with the Court as appropriate before trial begins on the day of their anticipated use.

27. Each party shall serve on opposing counsel by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered), full color copies of the

demonstrative exhibits each intends to use during direct examination of a witness by 7:00PM EDT on the calendar day before such direct examination is expected to take place. The receiving party shall inform the opposing party of any objections to such demonstrative exhibits by 9:00PM EDT of the day received, and the parties shall meet and confer by 10:00PM EDT that evening to resolve the objections. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit. Any disputes as to demonstrative exhibits to be used in a direct examination shall be raised with the Court as appropriate before trial begins on the day of their anticipated use.

28. This provision does not apply to demonstrative exhibits created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. In addition, blow-ups, enlargements, or highlights of exhibits or of parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

29. Complete legible copies of documents may be offered and received into evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or if in the circumstances it would be unfair to admit the copy in lieu of the original. Complete legible copies of United States and foreign patents and/or applications, and the contents of associated file histories, may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies.

VII. WITNESSES

A. Live Witnesses

30. Plaintiffs' list of fact and expert witnesses they may call at trial, either live or by deposition, is attached hereto as **Exhibit 8**.

31. Watson's list of fact and expert witnesses it may call at trial, either live or by deposition, is attached hereto as **Exhibit 9**.

32. Any witness not listed in **Exhibits 8 or 9** will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary.

33. On May 1, 2015, the parties will exchange final witness lists. For planning purposes, the parties will identify witnesses and which of those witnesses they expect to testify live and which they expect to testify by deposition at that time. Final designations of deposition testimony, counter-designations and objections thereto shall be exchanged in accordance with paragraph 38 below. The parties currently have a dispute regarding three witnesses.

- a) Watson wishes to call Dr. Herwig Buchholz, a live witness on Plaintiffs' witness list, as an adverse witness in its case-in-chief. Watson is willing to allow Plaintiffs' subsequent examination to go beyond the scope of Watson's examination, followed by re-cross, in order to prevent the necessity of having the witness testify twice. Plaintiffs object and believe Dr. Buchholz should testify in Plaintiffs' case-in-chief or, if appearing in Watson's case-in-chief should still be examined first by Plaintiffs. Watson objects.
- b) Watson wishes to compel Plaintiffs to produce Dr. Roland Martin, a witness by deposition on Plaintiffs' witness list, for live trial testimony to

be taken as an adverse witness under the same circumstances as offered with respect to Dr. Buchholz. Plaintiffs object.

- c) Plaintiffs seek to call Watson's expert Dr. Marsden as their own witness in their own case in chief. Watson objects.

34. The listing of a witness on a party's witness list does not require that party to call that witness to testify, either in person or by deposition.

35. Any witness not listed in **Exhibits 8 or 9** will be precluded from testifying, absent good cause shown.

36. Unless agreed to otherwise by the parties during trial, each party will provide to opposing party by electronic mail a written list of the names and order of witnesses who will testify live or by deposition by 7:00PM EDT two calendar days before the day the witness will testify. The other party shall identify any objections to such witness(es) by 7:00PM EDT the following day, and the parties shall meet and confer to resolve any objections by 9:00PM EDT that same evening. If good faith efforts to resolve any objections fail, the party objecting shall bring its objections to the Court's attention prior to the witness being called to the witness stand. Thereafter, each party shall update its list of expected witnesses by 7:00PM EDT at the end of each trial day.

B. Deposition Testimony

37. Deposition testimony that Plaintiffs may offer into evidence, together with Watson's counter-designations and the parties' objections to both, is identified in **Exhibit 10** hereto. Deposition testimony that Watson may offer into evidence, together with Plaintiffs' counter-designations and the parties' objections to both, is identified in **Exhibit 11** hereto. A key to the parties' objections to deposition designations is identified in **Exhibit 12** hereto. Reasonable supplementation deposition testimony will be permitted until May 11, 2015, at

5:00PM EDT. Objections to any such supplemental deposition designations shall be due no later than May 13, 2015, at 5:00PM EDT. The parties have a dispute regarding deposition designations:

- a) Plaintiffs have designated most of their affirmative deposition designations as counter-designations to be read at the same time as Watson's affirmative designations. Watson objects.

38. Unless otherwise agreed to by the parties during trial, each party shall provide notice of the final remaining lines and pages of each deposition transcript, prior to reading or playing a video of the deposition at trial (other than for impeachment of a witness or cross-examination) that a party intends to use at trial by 7:00PM EDT on May 15, 2015. The other party will identify any remaining objections to the designated testimony and any remaining pages and lines from that deposition to counter-designate by 7:00PM EDT on May 16, 2015. The parties shall meet and confer to resolve any objections to designated deposition testimony by 1:00PM EDT on May 17, 2015. If the objections to the disputed testimony cannot be resolved by the parties, the objections will be presented to the Court as appropriate before trial on the day of the testimony's anticipated use. The specified portions of the deposition shall be read or played in page/line order. If a party designates deposition testimony, and the other party counter-designated deposition testimony, both the designation and the counter-designation will be read or played in page order.

39. All irrelevant and redundant material, including colloquy between counsel and objections, will be eliminated when the deposition is read or viewed at trial.

40. The parties each reserve the right to offer deposition testimony designated by the other side (whether as a designation or a counter-designation) even if not separately listed on their own deposition designation list, subject to any evidentiary objections.

41. The parties will be charged for the time taken to read or play its designations according to the proportions to be provided by the parties.

42. The listing of a deposition designation does not constitute an admission as to the admissibility of the testimony nor is it a waiver of any applicable objection.

VIII. BRIEF STATEMENT OF INTENDED PROOFS

43. In support of their claims and in addition to the facts not in dispute, Plaintiffs expect to offer the proofs set forth in **Exhibit 13** hereto.

44. In support of their claims and in addition to the facts not in dispute, Watson expects to offer the proofs set forth in **Exhibit 14** hereto.

IX. IN LIMINE REQUESTS

45. Plaintiffs' *in limine* requests, along with Watson's oppositions thereto and Plaintiffs' replies, are set forth in **Exhibit 15** hereto. There is no **Exhibit 15**.

46. Watson's *in limine* requests, along with Plaintiffs' oppositions thereto and Watson's replies, are set forth in **Exhibit 16** hereto.

X. CERTIFICATION OF SETTLEMENT DISCUSSIONS

47. The parties have discussed aspects of settlement of this action. A settlement has not yet been reached.

XI. MISCELLANEOUS ISSUES

A. Proposed Amendment of the Pleadings

48. Neither party seeks to amend their pleadings at this time.

B. Stipulations

49. The parties' agreed stipulations for the case are attached hereto as **Exhibit 17**.

C. Damages

50. The parties do not intend to seek damages at this time.

51. Plaintiffs request the following relief from the Court:

- a) An order that United States Patent No. 6,441,168 B1 is infringed and not invalid;
- b) An order that the effective date of any approval of Watson's ANDA Nos. 203594 and 203593 be not earlier than the expiration date of the '168 patent;
- c) A permanent injunction against any infringement of the '168 patent by Watson, their officers, agents, attorneys, and employees, and those acting in privity or contract with them;
- d) A declaration that this case is exceptional under 35 U.S.C. § 285 and a grant of attorneys' fees to the Plaintiffs; and
- e) A grant of such other and further relief as this Court may deem just and proper.

52. Watson requests the following relief from the Court:

- a) A judgment declaring that Watson has not and does not infringe, directly, indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of United States Patent No. 6,441,168; that Watson has a lawful right to obtain FDA approval of ANDA Nos. 203593 and 203594; and further that Watson has a lawful right to manufacture, import, use, sell

and/or offer to sell its drospirenone, ethinyl estradiol, levomefolate calcium products in the United States once approved by the FDA;

- b) An judgment declaring that the asserted claim of United States Patent No. 6,441,168 B1 is invalid;
- c) An order that Plaintiffs/Counterdefendants, their parents and/or subsidiaries, and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Watson or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Watson, or charging any of them either orally or in writing with infringement of United States Patent No. 6,441,168 B1.
- d) A declaration that this case is exceptional under 35 U.S.C. § 285 and a grant of attorneys' fees to Watson; and
- e) A grant of such other and further relief as this Court may deem just and proper.

D. Expected Duration and Scope of Trial

53. Trial of this case is expected to take three (3) days, with the time being equally divided between Plaintiffs and Watson. Trial is scheduled to commence on May 18, 2015.

E. Type of Trial

54. This trial is a non-jury trial.

F. Order of Proof

55. The parties have agreed on the following order of proof: First, Watson shall present its affirmative case on invalidity. Second, Plaintiffs shall present their rebuttal case. Third, Watson shall present its rebuttal case.

XII. ORDER TO CONTROL COURSE OF ACTION

This Order will control the course of the trial and may not be amended except by consent of the parties and the Court, or by order of the Court to prevent manifest injustice.

DATED:

The Honorable Richard G. Andrews
UNITED STATES DISTRICT JUDGE

APPROVED AS TO FORM AND SUBSTANCE:

MORRIS, NICHOLS, ARSHT
& TUNNELL LLP

/s/ Derek J. Fahnestock

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com
dfahnestock@mnat.com

*Attorneys for Plaintiffs
Merck & Cie, Bayer Pharma AG and
Bayer HealthCare Pharmaceuticals Inc.*

OF COUNSEL:

Adam K. Mortara
J. Scott McBride
Rebecca T. Horwitz
Faye E. Paul
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Dated: May 5, 2015 - Original Filing Date
9128615
May 12, 2015 - Redacted Filing Date

POTTER ANDERSON & CORROON LLP

/s/ David E. Moore

Richard L. Horwitz (#2246)
David E. Moore (#3983)
Stephanie E. O'Byrne (#4446)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
sobyne@potteranderson.com

*Attorneys for Defendant
Watson Laboratories, Inc.*

OF COUNSEL:

Steven A. Maddox
Jeremy J. Edwards
Matthew C. Ruedy
MADDOX EDWARDS PLLC
1900 K Street NW, Suite 725
Washington, DC 20006
(202) 830-0707